BSI Standards Publication

Anaesthetic and respiratory equipment — Cuff pressure indication, control and regulation devices

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 23371:2022. It is identical to ISO 23371:2022.

The UK participation in its preparation was entrusted to Technical Committee CH/121/5, Airways and related equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2022

ISBN 978 0 539 01189 0

ICS 11.040.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 June 2022.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD **EN ISO 23371**

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2022

ICS 11.040.10

English Version

Anaesthetic and respiratory equipment - Cuff pressure indication, control and regulation devices (ISO 23371:2022)

Matériel d'anesthésie et de réanimation respiratoire - Dispositifs d'indication, de contrôle et de régulation de la pression du ballonnet (ISO 23371:2022)

Anästhesie- und Beatmungsgeräte - Manschettendruck-Anzeigegeräte (ISO 23371:2022)

This European Standard was approved by CEN on 17 March 2022.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 23371:2022 E

Contents

Page

European foreword **3**

European foreword

This document (EN ISO 23371:2022) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by December 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 23371:2022 has been approved by CEN as EN ISO 23371:2022 without any modification.

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 General requirements ... **2**
4.1 General ... 2
4.2 Alternative test methods ... 2

5 Materials ... **3**

6 Design requirements ... **3**
6.1 General ... 3
6.2 Metrological requirements ... 3
6.3 Connectors ... 4
6.4 *Integrated cuff pressure indicators* ... 4
6.5 Mechanical strength ... 5

7 Requirements for Cuff pressure indication, control and regulation devices supplied sterile ... **5**

8 Packaging ... **6**

9 Information supplied by the manufacturer ... **6**
9.1 General ... 6
9.2 Marking ... 6
9.2.1 General ... 6
9.2.2 Markings ... 6
9.3 Instructions for use ... 6

Annex A (Informative) **Rationale** ... **8**

Bibliography ... **9**

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document provides the essential performance and safety requirements for the design of *cuff* pressure indication and/or regulation devices for use with airway products. *Cuffs* on *tracheal tubes* and *tracheostomy tubes* are intended to seal and protect the trachea from aspiration of secretions and to provide an unobstructed airway in patients during spontaneous, assisted or controlled ventilation for short or prolonged durations. *Supralaryngeal airways* feature an inflatable *cuff* to provide a guide for insertion and stability of the airway. A variety of *cuff* designs are available to meet particular clinical requirements. *Cuffs* on *tracheal tubes* and *tracheostomy tubes* function by forming a seal between the *airway device* and the epithelial lining of the patient's airway. A pressure will be exerted on the lining of the airway where it makes contact with the *cuff*. Inflation of the airway *cuff* such that the pressure exerted on the epithelium is in excess of the capillary perfusion pressure can result in ischemia of the epithelium. This can result in short or long-term morbidity ranging from mild (e.g. sore throat) to severe (e.g. subglottic stenosis) [1]. Overinflated *cuffs* on *supralaryngeal airways* can cause injuries such as damage to the lingual, hypoglossal or recurrent laryngeal nerves in addition to arytenoid dislocation, haematoma, tongue swelling and cyanosis[2]. Uncontrolled low airway *cuff* pressure can also increase the risk of micro-aspiration and ventilator-associated pneumonia[3,4].

Tracheal tube and *tracheostomy tube cuff* pressures have traditionally been assessed by the clinician at the time of *cuff* inflation. Typically this is done by listening for a leak at the mouth while inflating the *cuff* with positive pressure applied to the airway until the user can no longer appreciate a leak. Evidence suggests that such methods of clinical assessment of airway *cuff* pressure are inaccurate[5]. A number of clinical guidelines now recommend the measurement of cuff pressure using a suitable device[6].

Throughout this document the following print types are used:

— Requirements and definitions: roman type;

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. The Normative text of tables is also in smaller type;

— *Terms defined in Clause 3: italic type.*

Anaesthetic and respiratory equipment — Cuff pressure indication, control and regulation devices

1 Scope

This document specifies essential performance and safety requirements for *cuff pressure indicators* used to indicate the *intracuff pressure* of *airway devices*, such as *supralaryngeal airways*, *tracheal tubes* or *tracheostomy tubes*.

This document is also applicable to devices that combine *intracuff pressure* indication with a method of *cuff* inflation (such as a syringe or pump). The device can also provide a method of automatically maintaining *cuff* inflation at a specific pressure or within a pressure range.

The requirements specified in this document apply to stand-alone *cuff pressure indicators* and those integrated into other medical devices (e.g. ventilators, anaesthesia workstations, etc.).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18190 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
airway device
device that provides a gas pathway to and from the patient's trachea

3.2
automatic cuff pressure regulator
integrated cuff pressure indicator (3.7) able to automatically control the *intracuff pressure* (3.8) of an *airway device* (3.1)

3.3
cuff
inflatable balloon attached to the *airway device* (3.1) near the *patient end* (3.9)